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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,283	07/18/2003	Robert Stem	UCSF-088CON2	4596

24353 7590 08/27/2004

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/622,283	STERN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kagnew H Gebreyesus	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 34-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 34-41 is/are rejected.
- 7) ☐ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-33 have been cancelled. Claims 34-41 present for examination.

The information disclosure statement filed on 02/27/2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Cancelled references in applicants IDS have not been considered. Copies of these references have not been provided with the present application or the parent application.

#### ***Claim Objections***

Claim 39 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 34 is drawn to a glycosylated human plasma hyaluronidase polypeptide the activity of which is inherent. Claim 39 is not further limiting the subject matter of claim 34 by stating that the hyaluronidase polypeptide is enzymatically active.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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2. Claims 34, 36, 37 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. These claims are directed to a genus of DNA molecules encoding any hyaluronidase polypeptide from plasma. The specification teaches only a partial structure of a single representative species of a plasma hyaluronidase polypeptide. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of hyaluronidase polypeptide. Furthermore, these claims lack sufficient domain structures identifying pertinent amino acid residues required for glycosylation, fatty acid modifications in addition to residues essential for the active site(s) or a plasma hyaluronidase polypeptide sequence that distinguish it from other hyaluronidase polypeptides.

4. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Afify et. al. who teach the purification of hyaluronidase from fresh human serum as starting material to apparent homogeneity in a two-step procedure. This enzyme has an apparent molecular weight of 59 kDa when assayed by SDS-PAGE. Given the similarity of the substrate (hyaluronic acid) used to assay hyaluronidase activity, (described in the materials and methods section of the above reference and the method described by the applicant's specification respectively), the examiner has drawn a correlation between the functional characterization of the native hyaluronidase polypeptide, and structural elements such as glycosylation and fatty acid modification as inherent properties of the native hyaluronidase polypeptide. As such the enzyme inherently meets the limitations of claims 35-38.

Claim 40 is rejected since the specific activity of the hyaluronidase in the reference above (Afify et.al. ) was defined as the difference in absorbance at 492 nm between samples with or without added hyaluronidase which was similar to what is disclosed on page 51 in the specification of the present application. While the assay used is 1000 times more sensitive in detecting than that of Afify et. al., the relative activity of the enzyme is presumed to be the same as the enzyme of Afify is the same enzyme taught by applicants and is disclosed by Afify as having been purified to homogeneity. When purified to homogeneity an enzyme acquires the maximum specific activity that is inherent to the enzyme itself.

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The references that are cancelled in the information disclosure citation (1449) are not considered for the current application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagne H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagne H Gebreyesus  
Art Unit 1652

